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DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

Food and Drug Administration
One Montvale Avenue
Stoneham, Massachusetts 02180
(617)279-1675 FAX: (617)279-1742

WARNING LETTER

June 26, 1997

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

NWE-09-97

Regina Kontoes, President
Dr. A. C. Daniels, Inc.
109 Webster Road
Webster, MA 01570

Dear Mrs. Kontoes:

During an inspection of your veterinary drug manufacturing firm (Dr. A. C. Daniels, Inc., 109 Webster Road, Webster, MA) on December 30, 1996 and January 2, 1997, our investigator confirmed that the following drug products are manufactured and distributed by your firm:

- B.E.L.L. Drops (for Adult Horses)
- Danilax Laxative (for Dogs and Cats)
- Hot Spot Lotion (for Dogs)

Under the Federal Food, Drug, and Cosmetic Act (the Act), any article intended for use

in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals, or is intended to affect the structure or function of man or other animals, is regarded as a "drug." Unless a drug is generally recognized by qualified experts as safe and effective for its labeled intended uses, it is a "new animal drug" under the law. A new animal drug may not be legally marketed unless it is the subject of an approved New Animal Drug Application (NADA). NADAs may be approved on the basis of adequate scientific data which the applicant submits as evidence of the safety and effectiveness of the product.

The products **Danilax, Hot Spot Lotion,** and **B.E.L.L. Drops for Adult Horses** are new animal drugs, which are adulterated under Section 501(a)(5) of the Act, in that they are new animal drugs which are unsafe within the meaning of Section 512 since no New Animal Drug Applications have been filed with the Food and Drug Administration, and they are not generally recognized as safe and effective for their labeled uses.

Furthermore, our investigator documented deviations from current Good Manufacturing Practice (cGMP) Regulations, which are set forth in Title 21, Code of Federal Regulations, Parts 210 and 211. These deviations cause your drug products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) in that the controls used for the manufacture, processing, packing, or holding of these products are not in conformance with cGMP regulations. The deviations documented by our investigator in support of this finding include the following:

- Failure to test bulk pharmaceutical chemicals prior to use in the manufacture of finished drug products.

- Failure to test all finished drug products prior to release for distribution.

- Failure to label finished drug products with expiration dates.

- Failure to verify suitability of testing methods under actual conditions of use.

Your letter of February 11, 1997 has been received and reviewed by our office. We have no objection to the proposed correction, although inspectional verification may be required to confirm compliance. Unapproved new animal drug issues and other GMP issues cited herein still need to be addressed.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act. Federal agencies are advised of the issuance of all Warning Letters concerning drugs so that they may take this information into account when considering the award of contracts. You should take prompt action to correct these deviations. Failure to do so may result in regulatory action by FDA without further notice.

Possible actions include seizure and/or injunction.

You should notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

You should direct your reply to the attention of Mark Lookabaugh, Compliance Officer at the following address:

Food and Drug Administration
New England District Office
One Montvale Avenue, 4th Floor
Stoneham, MA 02180

If you have any questions concerning this matter, please contact Mr. Lookabaugh at 617.279.1675 x118.

Sincerely,

[Sig]

James A. Rahto
Director
New England District